



**Roundtable on
Clinical Interventions for Cardiovascular Disease:
Enhancing Effectiveness**

Summary Report

**Vancouver, BC
March 25-26, 2010**



Introduction

Although gender and sex are known to influence drug adherence, absorption, and side effects as well as appropriate sizing of biomedical devices, clinical interventions tend to be gender and sex blind. Pharmaceuticals, devices, diagnostics, and clinical programs are generally not tested to determine if and how their effects may differ in women and men.

By identifying clinical interventions as one of the six strategic research directions in its 2009-12 Strategic Plan, the Institute of Gender and Health (IGH)—one of 13 institutes of the Canadian Institutes of Health Research—has committed to funding research that helps to ensure that these interventions are accessible, appropriate, and effective with respect to gender and sex.

On March 25 and 26, 2010, the IGH brought together leading researchers and experts representing diverse disciplines, research topics, and policy areas to Vancouver, British Columbia, to examine clinical interventions for cardiovascular disease (CVD)¹ through a sex and gender lens.

This roundtable was the IGH's first strategic initiative to advance the research agenda in this priority area. The IGH collaborated with a number of partners on this initiative, including the CIHR's Institute of Circulatory and Respiratory Health and Knowledge Translation Branch, the Drug Safety and Effectiveness Network, the National Strategy on Patient Oriented Research, and the Heart and Stroke Foundation of Canada.

Purpose and Objectives

The objectives of the roundtable were to

1. discuss the current state of research evidence regarding sex and gender differences in CVD and identify areas that can be translated into effective gender/sex-responsive clinical practices;
2. provide input on priority areas for further multidisciplinary research on gender, sex, and clinical interventions for CVD and identify knowledge gaps;

¹ CVD includes both cardiac disease and stroke.



3. provide input into the resources needed to advance research in clinical interventions for CVD that are tailored on the basis of gender and sex; and
4. facilitate multidisciplinary linkages, exchanges, and collaborative networks among experts in the field of clinical interventions for CVD.

Processes and Methods

Criteria for Selection

Five criteria were used by participants to identify priority topics for research on clinical interventions for CVD with respect to gender and sex:

1. Addresses critical² issues related to gender and sex dimensions of clinical interventions for CVD that have been identified by stakeholders, including knowledge translation (KT)
2. Draws and builds on Canada's strengths in research related to gender, sex, and clinical interventions for CVD
3. Has strong potential for significant impact on the health of Canadians through research, policy development, interventions, and KT activities
4. Helps address gaps in the current research situation related to gender, sex, and clinical interventions for CVD
5. Has strong potential for partnerships in which individuals, groups, CIHR institutes, and other organizations can work together collaboratively to leverage each other's intellectual capital, expertise, and resources

Research into Practice: Identifying Opportunities and Barriers

To help identify priority research topics, participants first appraised which existing gender, sex, and health research evidence was ready to be translated into cardiovascular (CV)

² In this context, "critical" means of highest importance, crucial, and where there is a crisis or turning point.



practice, including a number of preventive and rehabilitative interventions. They identified challenges associated with moving research into practice, including a lack of funding, clinician disengagement, poor uptake of information by patients, and insufficient inclusion of women/females in human and animal studies. Processes identified to address these challenges included the development of standardized patient outcome indicators and the infrastructure to support them, greater inclusion of women in cardiovascular research, more funding for “real-world” studies, and more research on sex- and gender-sensitive interventions targeted at at-risk populations.

Topic Summaries

After a facilitated discussion process, participants identified five priority topics based on the state of the research evidence for future research on clinical interventions for CVD with respect to sex and gender:

1. Effective KT strategies for CV health in women and men
2. Re-inventing CV risk across the continuum
3. Primordial to tertiary prevention: contextually-tailored, outcome-driven approaches
4. Sex-dependent mechanisms of CV health and disease
5. CV health outcomes: equitable access to effective care to achieve optimal outcomes

Cross-cutting themes that apply across all topic areas included the following:

1. Funding to support multidisciplinary teams/environments and for training new investigators (women in particular)
2. A life-course perspective
3. Incorporation of the social determinants of health (e.g., socio-economic, cultural, ethnic)

Topic 1: Effective KT Strategies for CV Health in Women and Men

This research topic focuses on improving patient care through the development and implementation of effective strategies for translating gender- and sex-related research evidence on CV health and disease into practice. It includes creating innovative tools to evaluate CVD processes and outcomes and the use of best practices across the spectrum of



care (e.g., through quality indicators, compensation, accreditation). Another objective of research in this topic area is to determine how best to communicate with the general public and at-risk populations about the prevention and management of CVD. Research in this topic area could examine ways to measure and improve the effectiveness of KT strategies for men and women across different regions, populations, and sub-populations.

Topic 2: Re-Inventing CV Risk across the Continuum

Determining the impact of sex and gender on CV risk across the continuum is the central theme of this priority topic. Both CVD and risk are regarded in the broadest possible sense; that is, CVD risk includes peripheral, heart, cerebrovascular, and other related effects and risks ranging from mortality to functional impairment and quality of life. Considerations in this topic area include the dynamics of time (short-, medium-, and long-term) and the spectrum of risk (high, medium, and low). Potential areas for research include examination of current risk-assessment tools and their validity for women and men and determination of whether clinicians' assessments are influenced by gender or sex biases. Also important is the identification of significant risk factors/markers and their impacts, and what factors affect changes in risk status. A key research question is whether risk assessment can be used to prevent or modify acute events through early intervention and, if so, which interventions would work best.

Topic 3: Primordial to Tertiary Prevention: Contextually-Tailored, Outcomes-Driven Approaches

The effectiveness of intervention strategies for preventing/managing CVD are influenced not only by gender and sex, but also by contextual factors such as culture/ ethnicity, geographic location, life course, physical and mental health, and socio-economic status. This research topic focuses on the development of primary, secondary, and tertiary strategies that are tailored to these contexts and aligned with sex- and gender-sensitive outcomes. Research in this area could examine the effectiveness of stress management programs in CVD and of gestational diabetes mellitus (DM)/pre-eclampsia postpartum strategies in the prevention of DM and hypertension; how sex/gender and other contextual factors affect access to and use of referrals; the effectiveness of chronic disease self-management programs; or sex/gender-



tailored health promotion activities (e.g., tobacco cessation programs) for adolescents and high-risk populations.

Topic 4: Sex-Dependent Mechanisms of CV Health and Disease

There are differences between males and females at the molecular, cellular, physiological, and pathophysiological levels with regard to CV health and disease. This research topic is focused on sex-related differences in the developmental origins of CVD across the lifespan—from gestation, through birth, puberty, menopause/andropause to old age—and how they affect health risks and responses to therapy. Research in this area could explore sex-dependent changes in aging related to CV health and disease, biological mechanisms of self-dependent response to therapy in CVD, and the impact of fetal programming and the sex of progeny on the development of CVD risk. Additional key study areas could include sex-dependent mechanisms of CVD (e.g., stroke), how therapeutic response is sex-determined, and the sex-dependent mechanisms of cellular function in CV health and disease, from cell to whole organism.

Topic 5: CV Health: Equitable Access to Effective Care to Achieve Optimal Outcomes

This research topic focuses on understanding how gender and sex influence access to care (e.g., clinician referral practices, organization of services, social determinants of health) across the continuum and life course for diverse populations. The ultimate goal of research in this area is to develop knowledge that will contribute to Canadians receiving equal access to the best possible CV health care. This topic area encompasses diagnosis and intervention at the primary, secondary, and tertiary levels of care as well as patient, provider, and institutional education. One focus of research is the development and evaluation of models to integrate and coordinate care within health systems and to create linkages to public health and other sectors. Possible areas of study include understanding barriers to access and designing and evaluating clinical, system, policy and population interventions to eliminate/minimize them. Research could also focus on developing, evaluating, and implementing the use of standardized gender- and sex-sensitive quality outcome indicators to assess performance in the provision of effective care to achieve optimal outcomes.



Requirements for Research and KT

Requirements to carry out work under these priority research topics include the formation of multidisciplinary teams, networks, and partnerships composed of relevant (including non-traditional) players. Linkages with partners are necessary to conduct research and KT as well as to leverage funding to support the development of innovative tools and initiatives, training strategies, and data. Specific initiatives that could benefit this work include a Canada-wide longitudinal study (e.g., “Framingham North”), pragmatic studies on specific communities, and a collaborative forum process to gauge progress and identify gaps.

Conclusion

The roundtable wrapped up with a discussion on the roles of researchers and the CIHR and its Institutes with respect to the inclusion of gender and sex in research and KT related to clinical interventions for CVD. It was recognized that budgetary constraints are a significant barrier when addressing sex and gender in analyses, because these approaches can require larger samples.

Participants agreed that the research community has a responsibility to raise the profile of this cross-cutting issue through several strategies, including

- holding informal discussions with colleagues;
- writing journal editorials or debate pieces drawing attention to gender, sex, and health issues;
- encouraging scientific journals to publish gender/sex-specific data;
- participating in speakers’ bureaus and public engagement activities;
- recognizing excellence in research and media-reporting on sex, gender, and health;
- promoting data development to enable identification of gaps and options for addressing them;
- creating linkages with other interested parties, such as industry and disease-specific groups; and
- making research ethics boards aware of sex and gender discrepancies.



It was suggested that the IGH could also help raise the profile of gender- and sex-specific issues related to CVD by helping to connect scientists with politicians and media and notifying researchers of ways to get involved in activities related to gender and health through the CIHR website and other means. Other potential roles for the IGH include developing funding opportunities that involve partnerships with the public sector (e.g., schools) in data collection and linking researchers with policy-makers in topic areas that are relevant to specific government strategies or programs under development. While controversial, it was also suggested that the inclusion of women in clinical trials be mandated as a condition for CIHR funding.



Appendices

Appendix I: Roundtable Agenda

	Thursday, March 25, 2010	Friday, March 26, 2010
0800	Breakfast	Breakfast
0900	<p>Welcome and Opening Remarks Dr. Joy Johnson, Scientific Director, Institute of Gender and Health</p> <p>Part I: The Context</p> <ul style="list-style-type: none"> - Welcome! - People and Process: Dorothy Strachan, Facilitator 	<p>Agenda: Review, Preview</p> <p>Feedback summary</p> <p>Part III cont'd</p> <p>Small group work:</p> <ul style="list-style-type: none"> - Review of draft report on Part III <p>Plenary discussions:</p> <ul style="list-style-type: none"> - Refining topics
1050	<p>The Context cont'd</p> <ul style="list-style-type: none"> - Experts in Action: Survey Results - Complexities - Clinical readiness <p>Part II: Criteria and Priorities</p> <ul style="list-style-type: none"> - Criteria for Priority Setting - Research Transfer Readiness - Identification of priority research topics 	<p>Part IV: Knowledge Translation</p> <p>Plenary discussion:</p> <p>Requirements for enhancing KT</p> <p>Closing Remarks</p> <p>Feedback on the Roundtable</p>
1200	Buffet Lunch	
1300	<p>Part III: Research Topics and Funding Opportunities</p> <p>Small group work:</p> <ul style="list-style-type: none"> - Topic description - Related challenges, gaps, opportunities 	Lunch
1520	<p>Part III cont'd</p> <ul style="list-style-type: none"> - Potential research questions - Supportive funding opportunities - Knowledge Translation and Exchange <p>Plenary:</p> <ul style="list-style-type: none"> - Presentations and discussions: refining small group work 	
1650	Feedback on the Day	
1700	Closing	



Appendix II: List of Participants

Name	Title	Affiliation
Dr. Beth Abramson	Associate Professor	St. Michael's Hospital, University of Toronto
Dr. Sonia Anand	Professor	McMaster University
Dr. Paul Wayne Armstrong	Distinguished University Professor	University of Alberta
Dr. Arlene Bierman	Associate Professor & OWHC, Chair in Women's Health	St Michael's Hospital and University of Toronto
Dr. Stephanie J. Brister	Associate Professor	Faculty of Medicine, University of Toronto
Mrs. Sally Brown	CEO	Heart and Stroke Foundation of Canada
Dr. Lorraine Chalifour	Associate Professor	Faculty of Medicine, McGill University
Dr. Alex Clark	Associate Professor	University of Alberta
Mrs. Tracey Colella	Advanced Practice Leader	Toronto Rehabilitation Institute
Dr. Michael Paul Czubyrt	Associate Professor	Faculty of Medicine, University of Manitoba
Dr. Bianca D'Antono	Research Associate	Faculty of Medicine, Université de Montréal
Dr. Céline Fiset	Professor	Faculty of Pharmacy, Université de Montréal
Mrs. Abby Forson	Assistant Director	CIHR Institute of Gender and Health
Dr. Sherry L. Grace	Associate Professor	Faculty of Health, York University
Dr. Lorraine Greaves	Executive Director	Ontario Ministry of Health
Dr. Michael Hill	Associate Dean Clinical Research	Faculty of Medicine, University of Calgary
Dr. Karin Hartmann Humphries	Director, Evaluation & Research	Cardiac Services and BC Cardiac Registry
Dr. Joy Johnson	Scientific Director	CIHR Institute of Gender and Health
Dr Chris Kaposy	Assistant Professor	Faculty of Medicine, Memorial University of Newfoundland
Dr. Nadia Ahmed Khan	Assistant Professor	Faculty of Medicine, University of British Columbia
Dr. Lyne Lalonde	Associate professor	Faculty of Pharmacy, Université de Montréal
Mrs. Tina Lawton	Project Manager	CIHR Institute of Circulatory and Respiratory Health
Dr. Martha Mackay	Clinical Assistant Professor & Clinical Nurse Specialist	School of Nursing, University of BC & Heart Centre, St. Paul's Hospital
Dr. Nancy Elizabeth Mayo	Professor	Faculty of Medicine, McGill University
Dr. Colleen Norris	Associate Professor	Faculty of Nursing, University of Alberta



Institute of Gender and Health

Name	Title	Affiliation
Dr. Sylvie Perreault	Associate professor	Faculty of Pharmacy, Université de Montréal
Dr. Louise Pilote	Professor	McGill University
Dr. Pamela A. Ratner	Professor	School of Nursing, University of British Columbia
Dr. Annie Rochette	Assistant Professor	Faculty of Medicine, Université de Montréal
Dr. James William Scholey	Professor	Faculty of Medicine, University of Toronto
Dr. Donna Stewart	Professor	University Health Network, University of Toronto & IGH Institute Advisory Board Member
Dr. Joan Elizabeth Tranmer	Associate Professor	Faculty of Health Sciences, Queen's University
Dr. Michele Turek	Associate professor	Faculty of Medicine, University of Ottawa
Dr. Michael Tymianski	Director, Cerebrovascular Therapeutics Program	University Health Network, University of Toronto